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Improving Asthma-Related Health Outcomes Among Low-Income, Multiethnic, School-aged Children: Results of a Demonstration Project That Combined Continuous Quality Improvement and Community Health Worker Strategies

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ABSTRACT

OBJECTIVE. The purpose of this work was to improve asthma-related health outcomes in an ethnically and geographically disparate population of economically disadvantaged school-aged children by using a team-based approach using continuous quality improvement and community health workers.

PATIENTS AND METHODS. A demonstration project was conducted with 7 community clinics treating ~3000 children with asthma 5 to 18 years of age. The overall clinic population with asthma was assessed for care-process changes through random cross-sectional chart reviews at baseline and 24 months ($N = 560$). A subset of patients with either moderate or severe persistent asthma or poorly controlled asthma ($N = 405$) was followed longitudinally for specific asthma-related clinical outcomes, satisfaction with care, and confidence managing asthma by family interview at baseline and at 12 or 24 months. Patient-centered and care-process outcomes included patient/parent assessment of quality of care and confidence in self-management, asthma action plan review, and documentation of guideline-based indicators of quality of care. Direct clinical outcomes included daytime and nighttime symptoms, use of rescue medications, acute care and emergency department visits, hospitalizations, and missed school days. Each clinic site's degree of adherence to the intervention model was evaluated and ranked to examine the correlation between model adherence and outcomes.

RESULTS. Cross-sectional data showed clinic-wide improvements in the documentation of asthma severity, review of action plans, health services use, and asthma symptoms. At follow-up in the longitudinal sample, fewer patients reported acute visits, emergency department visits, hospitalizations, frequent daytime and nighttime symptoms, and missed school days compared with baseline. More patients reported excellent or very good quality of care and confidence in asthma self-management. Linear regression analysis of the clinical sites' model adherence ranks against site-level combined scores estimating overall outcomes, clinical outcomes, and improvements in clinical care processes showed significant linear correlations with $R^2 \geq 0.60$.

CONCLUSIONS. The demonstration produced major improvements in asthma-related care processes and clinical outcomes. Closer adherence to the demonstration model was directly associated with better outcomes.

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Key Words

asthma, school-aged children, chronic care model, continuous quality improvement, CHW, clinical outcomes, care-process outcomes, model adherence

Abbreviations

CQI—continuous quality improvement
CHW—community health worker
NAEPP—National Asthma Education and Prevention Program
TA—technical assistance

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ASTHMA IS THE most common chronic disease of childhood. Its prevalence has been estimated to have increased over the past few decades, with major deleterious effects on children's morbidity, mortality, missed school days, and missed work days for parents.¹ Low-income and minority children are well known to be disproportionately affected by the illness.² These children are often treated in emergency and urgent care facilities on an episodic basis, leaving them with inadequate preventive maintenance strategies and resulting in frequent visits for care and the at-times-dangerous overusage of rescue medications.³

The optimal management of asthma is frequently compromised by the lack of a comprehensive clinical management program.⁴ Multidimensional programs, following selected aspects of the Chronic Care Model outlined by Wagner,⁵ have not been widely instituted or tested in clinics serving low-income, ethnically diverse populations of school-aged children. Ideally, such programs would emphasize multiple elements including, among others: improved clinical care processes, programmatic incentives for making appropriate changes in care delivery systems, patient and family education and support of disease self-management, improved organization of practice systems and practice team functions, and the use of evidence-based clinical practice guidelines through provider education.⁵ Compliance with national asthma care guidelines has been found to be relatively low, including in the pediatric Medicaid population.⁶⁻⁹

Our hypothesis was that effecting changes in the overall system of care for childhood asthma in community clinics, using a combination of such strategies that have previously been reported to positively contribute to asthma health outcomes, would lead directly to improved quality of care and clinical outcomes for patients, as well as increased confidence in self-management of asthma and greater family satisfaction with care. In formulating this multifaceted demonstration, we designed a comprehensive program intended to rationally influence many aspects of the clinical management of asthma in a population of children served in community clinics.

The intervention involved the introduction of a continuous quality improvement (CQI) process, used by a multidisciplinary clinic-based team, including community health workers (CHWs). The goals were to promote multidisciplinary team building, create evidence-based improvements in clinic systems and processes, and provide clinical care in accordance with National Asthma Education and Prevention Program (NAEPP) guidelines.^{1,10,11} CHWs were employed to foster patient and team communication, patient and parent education, and to conduct home visits, which included an environmental assessment.^{12,13}

The target population of the intervention was children aged 5 to 18 years with asthma who received clinical care at 7 high-volume Medicaid ("Medi-Cal")

provider community clinics in California. We measured care-process and self-management outcomes to assess intervention-related changes in clinical practice and their effect on childhood asthma-related health outcomes.

METHODS

Study Population and Design

The California Asthma Among the School Aged (CAASA) project was conducted from 2001 to 2004 at 7 geographically diverse, high-volume nonprofit California community clinics of which the patients are multi-ethnic, low income, and primarily Medicaid or other public insurance enrollees or uninsured. Four of the clinics were not-for-profit, nongovernmental community clinics located in Fresno, Madera, Los Angeles, and San Diego counties; 2 were county-run public health clinics in Contra Costa and Riverside counties; and 1 was a city-owned community clinic in Imperial County. Both agricultural centers and urban regions of the state were represented by this sample of clinics, which served a range of between ~100 and >1000 children with asthma annually. Baseline and follow-up measures derived from cross-sectional site-level chart reviews and longitudinal patient-level interviews were obtained and compared. The former were used to assess the degree to which clinic practices consistent with NAEPP guidelines were applied across the sites' populations of school-aged children with asthma (eg, documentation of selected clinical variables in the medical chart), whereas the latter were used to assess individual patients' clinical outcome changes over time (eg, acute clinic visits and symptom frequency). The demonstration protocol was approved by the University of California at San Francisco Committee on Human Research.

Patients were selected consecutively by site physicians at clinic visits to be part of the longitudinal cohort if they had moderate or severe persistent or poorly controlled asthma; were 5 to 18 years of age; and had ≥ 1 clinic visit in the previous year ($n = 541$; mean patients per site: 77). Potential project enrollees were identified by clinic staff from new-to-the-clinic patients, administrative claims data, existing patient lists, affiliated managed care organizations, emergency departments, hospitals, and urgent care clinics. All had a clinic visit for eligibility assessment before enrollment in the project.

Chart reviews were completed on 40 patient records at each site ($n = 280$). They were selected at random both at baseline and 24 months later from the population of school-aged patients who had been seen for asthma at least once within the previous 12 months. Changes in patient-level outcomes were assessed by comparing data from baseline and follow-up interviews at 12 (49% of total) or 24 months (51% of total), depending on the timing of a patient's enrollment. A total

of 405 patients (75%) completed follow-up interviews. Of the patients who were not followed, 48 were unable to be contacted after multiple attempts, 45 moved out of the area, 26 refused the follow-up interview, 8 did not appear for the interview, 8 were contacted for an interview but not scheduled, and 1 respondent died in an incident unrelated to asthma.

Intervention

The demonstration's key components were a team-based CQI process implemented at each clinic, combined with the addition of a CHW. A CHW was employed at each site to provide linkages among patients' clinical providers, home situation, school environment, and the larger community in which they resided.

Support for the 7 clinics was provided by a central technical assistance (TA) team that facilitated the formation of each site's CQI team, introduced and provided oversight and monitoring of the clinic-level CQI process, facilitated the implementation of techniques to assess the effects of changes in clinical care processes, and evaluated the implementation of the model and measured demonstration outcomes. Explicit goals for clinical management processes and outcomes were based on NAEPP guidelines and were agreed on by each site's CQI team.

Continuous Quality Improvement

Multidisciplinary CQI teams were formed at each site and included a "clinician champion" (a physician or nurse practitioner), a CHW, a project coordinator, and other clinical and nonclinical staff (physicians, nurses, other caregivers, and administrative staff). These teams developed, implemented, and evaluated clinic-specific care-process changes using a systematic data-driven CQI process. Site-specific interventions were based on assessments by staff from each clinic of needed care-process improvements. The TA provided (see below) ensured that the CQI process was consistently applied.

Examples of site-specific care-process changes that were implemented include the introduction of asthma visit flow sheets, the use of asthma action plans, the creation of clinician "pocket guides" for quality asthma care, clinic site-level provider and staff training on NAEPP asthma guidelines, and the creation of strong communication links with local schools and other community-based organizations. Each of the CQI teams met in person at their sites at least monthly and with all of the other site teams and the TA team by monthly teleconferences. CQI interventions and their effect on 13 NAEPP-recommended asthma care quality indicators derived from 10 randomly selected charts at each site were reported to the sites' CQI teams and the TA team on a monthly basis. The complete details of methods, quality indicators, educational materials, and other demonstration components can be found at <http://arcc.ucsf.edu/caasa>.

This information was available to the participating clinics during the project period.

Community Health Workers

Each of the 7 sites recruited ≥ 1 CHW to allow greater outreach to patients in their homes and communities. CHWs were responsible for providing asthma education to patients and families, community referrals (eg, smoking cessation programs for parents, housing authorities for mold and mildew abatement, school health educators, etc), and ≥ 1 home visit with home environmental assessment and environmental remediation information. CHWs were also an integral part of each site's CQI team.

TA Team

Ongoing and consistent TA was provided to each site CQI team to guide and support the demonstration intervention during the course of the project. The TA team included a project director, coordinator, database manager, and an epidemiologist/evaluator. Emphasis was placed on education, communication, documentation, evaluation methods, feedback, and using data as a primary driver to determine specific clinical quality improvement efforts. The TA team provided each site with (1) explicit goals derived from the NAEPP guidelines, (2) ongoing assistance and oversight to ensure consistent application of the CQI model, (3) guidance in the process of identifying, implementing, and evaluating new interventions and selectively affirming ones already in use, (4) effective methods for CHWs to work with patients and families, and (5) reporting processes, tools, and forms. This TA was provided through (1) semiannual all-site training meetings, (2) annual site visits, (3) tailored individual site training opportunities, (4) monthly teleconferences, (5) individualized written and verbal feedback to each site on monthly written progress reports submitted by each site, (4) a Web site (see above) that included numerous asthma management resources, and (5) training on asthma assessment and management issues from outside experts via the monthly conference calls and the semiannual all-site training meetings.

Data Collection and Outcome Measures

Data were collected for the longitudinal patient sample by using closed fixed-response interviews conducted by the project CHWs. For the cross-sectional sample, chart reviews were conducted by site project managers using a standardized chart-review protocol. To ensure consistency and accuracy in data collection, interviewers and chart reviewers were provided extensive training in data collection and the research protocol, as well as a research data collection manual for reference.

Patient and parent participation in the project was voluntary. Written informed consent was obtained for all of the participants and their primary caregivers in the

interview sample. Children older than 6 years were asked if they assented to participation as a part of the enrollment process. Interviews were conducted with the patient or primary caregiver (depending on the ability of the child to answer the interview questions) at the clinic or in the patient's home.

Data collected during the interview included patient and family demographics; frequency of asthma symptoms; health care use; missed school and parental work days; medications prescribed and used; annual influenza vaccination; environmental tobacco smoke exposure; changes made to the home environment; whether an action plan was created or reviewed at the last visit; whether the patient had a peak expiratory flow meter; confidence to manage asthma; and rating the quality of asthma care provided. Data collected in the chart reviews included patient demographics, prescribed medications, and documentation at the most recent asthma visit of daytime and nighttime symptoms, health care use, influenza vaccination, whether the provider asked about environmental tobacco smoke exposure, asthma severity classification, whether an asthma action plan was created, updated, or reviewed, and whether a copy was provided to the patient. In the final data analysis, all of the ordinal variables were dichotomized.

In addition to evaluating the separate outcome measures listed above, we combined them to create several aggregate site-level measures of the intervention effect. This procedure averaged out each site's wide variation between indicators and resulted in summary outcome measures that could be compared between sites. We calculated a mean overall outcome rank per site from the interview data using all of the variables presented herein, except the data on the administration of influenza vaccine, because site comparisons were unreliable because of selective shortages of influenza vaccine during the project period. For each of these variables, we calculated the relative improvement score for each site by using the number of patients who improved as the numerator (ie, patients who went from a poor result at baseline to a good result at follow-up) and the sum of patients who improved or got worse as the denominator. The sites were then ranked according to these improvement scores, and a mean overall outcome rank was calculated across indicators for each site. Similarly, we calculated (1) a mean clinical outcome rank (ie, any acute event, daytime and nighttime symptoms, missed school, and use of rescue-type medications), (2) a mean symptom rank (daytime and nighttime symptoms and use of rescue medications), (3) a health care use rank (any acute event), (4) a mean confidence and quality-of-care rank (confidence in managing asthma and rated quality of care), and (5) a mean process outcome rank (action plan, severity documentation, and peak expiratory flow meter).

For the chart-review data set, we calculated a mean

overall outcome rank using the chart-review documentation variables noted above, again with the exception of influenza vaccine administration. For each variable, the relative change was calculated by dividing the difference in the number of charts showing documentation at baseline and follow-up by the "room for improvement" (ie, 40 minus the number of charts with documentation at baseline). Sites were ranked according to this relative change, and a mean rank was calculated across indicators for each site.

For purposes of estimating the strength of the relationship between the degree of adherence to the intervention model and outcomes, we constructed an empirical, weighted "model adherence score," which was calculated for each site based on 16 scored objectives within 4 general categories: (1) application of the CQI process (weighted at 30% of total); (2) CQI leadership (30%); (3) appropriate use of outcome measurements (20%); and (4) integration of the CHW into the CQI process (20%). The weighting of the categories was a reflection of the literature that strongly supports these as predictors of successful CQI processes.^{11,14-19} Each of the 16 scored items described optimal systems and processes such as, for example, "clinic has CQI team with appropriate representation specific to all CQI interventions," "clinic administration is supportive of the CQI processes and interventions," and "the team utilizes a measurement process with customized indicators to accurately track intermediate steps toward a goal." After the individual sites had reached a steady state of operations (ie, the CQI team structure and processes and the CHWs were in place and functioning), the project director and coordinator independently ranked whether each site met, partially met, or failed to meet the CQI parameters noted above. These assessments were completed months before any site-level follow-up data were available. The site scores were evaluated again at the end of the intervention period by the same persons and were essentially unchanged with respect to both score and ranking (data not shown).

Statistical Analysis

For the longitudinal interview (paired) data set, the McNemar test and the test of symmetry were used. Bivariate analysis for the random chart-review data set was performed by using a 2-sample *t* test, the χ^2 test, and Fisher's exact test, as appropriate. Stepwise logistic regression for the chart-review data set was initiated using all of the demographic variables, including race/ethnicity and health care coverage, the potential intervention effect, and the site effect.

Because asthma severity was assessed in only 37% of patients at baseline, the inclusion of this parameter in the stepwise model resulted in a significant loss of study subjects. Therefore, the stepwise regression was run both with and without baseline asthma severity, and the re-

sults were compared. The parameter was found to be a significant predictor only for the action plan indicator, did not change the *P* value, and only slightly impacted the adjusted odds ratio for the intervention effect when compared with the model without asthma severity. As such, we report only the results for the models without asthma severity.

The final equation used for each response variable included the intervention effect and covariates that met a <.05 significance criterion. We tested for effect modification by including interaction terms in the models. These were kept in the model if the associated *P* value was <.05. However, when model validity became questionable on inclusion of the interaction term between intervention and site (because ≥ 1 site had a result of 0% or 100%), the interaction was not included, thereby averaging across sites, each of which performed the same number of chart reviews.

To investigate whether there was a correlation between outcomes and adherence to the intervention model, we performed simple linear regression analyses, regressing the various mean outcome ranks against the model adherence rank and the mean clinical outcome ranks against the process outcome ranks. No other covariates were included in these models. All of the statistical analyses were performed with SAS 8.2 (SAS Institute, Inc, Cary, NC).

RESULTS

The 7 sites were treating an overall population of ~3000 children with asthma throughout the study. Table 1

displays demographic and clinical characteristics of the longitudinal interview (*N* = 405) and chart-review (*N* = 560) samples at baseline and follow-up. In the longitudinal cohort, only the asthma severity rating changed significantly over time, shifting toward the less severe classifications of the disease. Although it was not an explicit study goal to reduce the asthma severity ratings, this trend is not unexpected, because over time, improvements in care can result in reclassification toward less severe levels. In the random chart-review sample, we found a slight but significant difference for race/ethnicity and health care coverage when comparing patients at baseline and follow-up. In the overall patient population, the percentage of white patients decreased from more than 13% to just less than 8%, whereas patients in the "other" race/ethnicity category increased by ~4%. At the individual clinic level, only 2 clinics showed a significant shift in race/ethnicity distribution, one showing an increase in black patients and the other a decrease in white patients and an increase in patients with an "other" ethnicity. With regard to health care coverage, there was a significant decrease in uninsured patients overall. At the clinic level, there was a statistically significant reduction in uninsured patients at 1 site only.

In the longitudinal interview sample, 25% of the patients were lost to follow-up. This proportion was lower than expected given the highly mobile population served by the clinics. The follow-up group contained more boys, more Medicaid insured, fewer uninsured, more Hispanic, and slightly less severe asthma patients

TABLE 1 Demographic and Clinical Characteristics

Indicator	Interview Sample					Chart-Review Sample				
	Baseline		Follow-up		<i>P</i> ^a	Baseline		Follow-up		<i>P</i> ^a
	<i>n</i>	Measure, %	<i>n</i>	Measure, %		<i>n</i>	Measure, %	<i>n</i>	Measure, %	
Male gender	405	60.3	—	—	—	280	61.4	280	64.3	.54
Race/ethnicity	405					280		280		.042
Black	—	14.3	—	—	—	—	16.4	—	18.2	—
Hispanic	—	81.7	—	—	—	—	66.1	—	66.1	—
White	—	2.2	—	—	—	—	13.6	—	7.9	—
Other	—	1.7	—	—	—	—	3.9	—	7.9	—
Health care coverage	405		405		.23	280		280		.004
None	—	10.6	—	11.6	—	—	13.2	—	7.5	—
California Kids	—	0.7	—	1.2	—	—	0.7	—	0.7	—
Healthy Families	—	8.6	—	11.9	—	—	9.6	—	12.9	—
Medi-Cal	—	75.1	—	69.9	—	—	52.1	—	60.7	—
Private	—	4.7	—	3.2	—	—	23.6	—	15.0	—
Other	—	0.3	—	2.2	—	—	0.7	—	3.2	—
Severity classification	381		387		.0017	104		194		.66
Mild intermittent	—	16.8	—	23.0	—	—	47.1	—	40.2	—
Mild persistent	—	32.6	—	36.7	—	—	27.9	—	33.0	—
Mod persistent	—	46.5	—	37.7	—	—	24.0	—	24.7	—
Severe persistent	—	4.2	—	2.6	—	—	1.0	—	2.1	—
Age, y	405	10.1 (9.9) ^b	—	—	—	280	10.8 (10.5) ^b	280	11.0 (10.9) ^b	.53

— indicates no data.

^a Data are comparing baseline with follow-up.

^b Data are mean (median).

than the group lost to follow-up ($P < .05$). The groups did not differ significantly at baseline in clinical and care-process outcomes (self-reported health care use, asthma symptoms, missed school, review of action plan, or documentation of asthma severity).

Care-process outcomes at baseline and follow-up in the chart-review sample were compared and are presented in Table 2. For every care-process indicator, highly significant improvements at follow-up were found for the combined site-level data, including documentation of acute visits, emergency visits, hospitalizations, daytime and nighttime symptoms, influenza vaccination in the past 12 months, asthma severity classification, and creation, updating, or review of asthma action plans. The adjusted odds ratios for improvement in care-process outcomes ranged between 4 and 18.

Plots representing the preintervention and postintervention measures for each clinic of asthma-related clinical outcomes, as well as family ratings of quality of care and confidence in patient/parent self-management of asthma, are presented in Fig 1. Overall, patients with hospitalizations decreased by four fifths (8.6% [before] vs 1.7% [after]); patients with an acute care visit for asthma exacerbation (48.1% [before] vs 17.3% [after]), an emergency department visit (26.9% [before] vs 8.6% [after]), or who missed school (37.8% [before] vs 11.8% [after]) decreased by approximately two thirds, as did the number of children with frequent daytime symptoms (51.6% [before] vs 16.0% [after]), frequent nighttime symptoms (47.2% [before] vs 18.0% [after]), and frequent use of rescue medications (42.3% [before] vs 11.8% [after]). Families who assessed the quality of care

as excellent or very good (57.0% [before] vs 78.8% [after]) and those who reported confidence in being able to manage their asthma (64.9% [before] vs 88.1% [after]) rose by more than one third. The P value was $<.0001$ for all of the paired comparisons.

The effect of the intervention on the measured outcomes differed significantly among the 7 sites. This is shown in Fig 1 for clinical outcomes in the interview sample and was demonstrated in the chart-review sample by a significant interaction term between intervention and site for all of the chart-review outcome indicators except documentation of the administration of influenza vaccine. Because of this between-site variation in outcomes, we were able to compare each site's outcomes to its ranked adherence to the intervention model by linear regression analysis, as presented in Table 3. A significant linear relationship ($R^2 = 0.61$; $P = .037$) was found for the longitudinal interview data between the sites' model adherence rank and the mean overall outcome rank (composed of all of the clinical and care-process outcomes), indicating that patient outcomes improved in direct proportion to compliance with the demonstration components.

A similar linear relationship existed between the mean symptom rank and the model adherence rank ($R^2 = 0.68$; $P = .023$), as well as between the mean process outcome rank (measuring compliance with the NAEPP guidelines) and the model adherence rank ($R^2 = 0.62$; $P = .035$). We also found a similar and significant linear relationship between clinical outcomes and care-process outcomes when regressing the mean clinical outcome rank against the mean process outcome rank ($R^2 = 0.64$;

TABLE 2 Care-Process Outcomes: Chart-Review Sample

Indicator	Baseline ($n = 280$), %	Follow-up ($n = 280$), %	Adjusted OR (95% CI) ^a	P
Documentation at the last visit of frequency of acute office/clinic visits in past 6 mo	29.6	78.6	18.1 (10.8–30.4) ^{b,c}	$<.0001$
Documentation at the last visit of frequency of emergency department visits in past 6 mo	20.7	49.3	7.33 (4.5–11.9) ^b	$<.0001$
Documentation at the last visit of frequency of hospitalizations in past 6 mo	18.6	43.6	6.6 (4.0–11.0) ^b	$<.0001$
Documentation at the last visit of frequency of daytime symptoms in the past 2 wk	46.1	68.9	4.3 (2.6–7.2) ^b	$<.0001$
Documentation at the last visit of frequency of nighttime symptoms in the past 2 wk	39.6	57.9	4.1 (2.4–6.9) ^b	$<.0001$
Documentation at the last visit of severity classification	37.1	69.3	6.6 (4.0–10.9) ^{b,c}	$<.0001$
Documentation at the last visit that a written action plan was created or existing plan updated or reviewed	15.0	43.2	7.8 (4.6–13.1) ^b	$<.0001$
Documentation of receipt of influenza vaccine in the past 12 mo	17.1	48.6	6.9 (4.4–11.1) ^b	$<.0001$

OR indicates odds ratio; CI, confidence interval.

^a Only the odds ratio for the intervention effect is shown, not for covariates or interaction terms.

^b Clinic is a significant covariate.

^c Health care coverage is a marginally significant covariate.

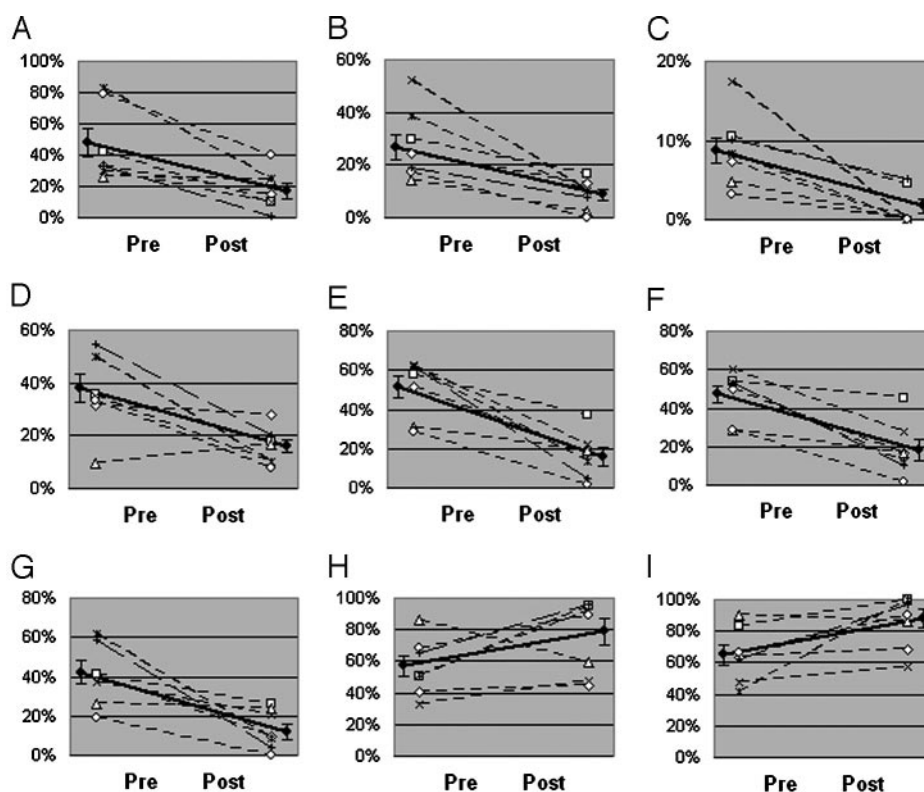


FIGURE 1

Childhood asthma clinical outcomes. A, Acute care visits (≥ 1 visit resulting from asthma in past 6 months); B, emergency department visits (≥ 1 visit in past 6 months); C, hospitalizations (≥ 1 hospital admission in past 6 months); D, school days missed (≥ 1 day missed as a result of asthma in past 6 months); E, daytime symptoms (more than twice per week in past 2 weeks); F, nighttime symptoms (more than twice per week in past 2 weeks); G, rescue-medication use (more than twice per week in past 2 weeks); H, very good/excellent care rating (patient/family rates asthma care as excellent or very good); I, asthma management confidence (patient/family feels confident managing asthma). Each clinic site is represented in the preintervention (pre) and postintervention (post) periods with a matched pair of symbols connected by a dashed line. The overall mean for the preintervention and postintervention groups of clinics \pm SE is represented by a heavy line with the ends slightly displaced from the individual clinic data for clarity.

TABLE 3 Linear Regression Models: Interview Sample

Model	Components	R^2	P
Overall outcome rank vs model adherence rank	Any acute event, missed school, day symptoms, night symptoms, use of rescue medication, confidence, quality of care, action plan reviewed, severity documented, PEF meter vs model adherence	0.61	.037
Symptom rank vs model adherence rank	Day symptoms, night symptoms, use of rescue medication vs model adherence	0.68	.023
Process outcome rank vs model adherence rank	Action plan reviewed, severity documented, PEF meter vs model adherence	0.62	.035
Clinical outcome rank vs process outcome rank	Any acute event, missed school, day symptoms, night symptoms, use of rescue medication vs action plan reviewed, severity documented, PEF meter	0.64	.031
Symptom rank vs process outcome rank	Day symptoms, night symptoms, use of rescue medication versus action plan reviewed, severity documented, PEF meter	0.65	.029

PEF indicates peak expiratory flow.

$P = .031$), as well as the mean symptom rank against the process outcome rank ($R^2 = 0.65$; $P = .029$).

DISCUSSION

The multidimensional demonstration intervention produced improvements over time in asthma care processes

and consequent clinical outcomes in an economically disadvantaged, multiethnic, geographically dispersed group of school-aged children. Taken together, the results support our primary hypothesis. Cross-sectional chart-review data revealed significantly improved asthma care across the entire school-aged clinic popula-

tion. Longitudinal data examining a sample of 405 children from 7 clinics showed clinically and statistically significant reductions in health services use, asthma symptoms, and missed school days.

The specific intervention components selected for this demonstration had been shown to be effective in previous studies.^{12,13,20,21} Our goal was to demonstrate and potentially increase the effectiveness of these CQI and CHW strategies by combining them and translating them “in the field” to practical applications in community clinics. Funding for the project was granted explicitly to pay for improved asthma care for the children involved in the demonstration and could not be used to support a control group. The resulting preintervention and post-intervention, nonblinded design made it impossible to directly quantify the exact extent of regression to the mean or other temporal effects on the observed improvements in clinical outcomes. This limitation also raises the possibility that bias may have been introduced as a result of patients giving desirable answers in response to questions asked by those who had been involved in their care over time.

Some degree of regression to the mean is expected when patients with a chronic disease are recruited for a study, especially if they are selected because of recent high health services use or during an acute phase of illness. The underlying question is whether regression to the mean accounts for a large portion of the observed improvements. We believe that this is unlikely in this demonstration for 4 reasons. First, patients were relatively stable children with ongoing asthma who were not chosen because of an acutely ill state or on the basis of a recent hospitalization or acute care visit for asthma. They were enrolled in the demonstration because they were clinically judged to have persistent or poorly controlled asthma.

Second, improvements in outcomes observed in this demonstration are greater than improvements reported in the control groups of previous trials that were presumably a result of regression to the mean or other temporal effects.²²⁻³¹ This is significant, because most control groups have been composed of sicker children who should have had a greater tendency toward regression to the mean than children in our demonstration who generally were not acutely ill. Wherever we were able to directly compare our clinical outcome measures with the intervention groups in controlled pediatric asthma trials that reported effective interventions, we found levels of improvement that were either similar or greater.^{22,24,32} The outcome effects that we observed were sufficiently favorable so that even when we hypothetically diminished our observed preintervention and postintervention improvements by more than half, the diminished improvements remained highly statistically significant (data not shown).

Third, we also assessed the clinics’ degree of adher-

ence to the intervention model, ranked the adherence scores on a clinic-by-clinic basis, and regressed the adherence scores against the ranked outcome scores. The correlation obtained was both highly significant and unexpectedly large in magnitude, especially when considering the in-the-field nature of the demonstration and the intrinsic heterogeneity of the populations studied. This strong correlation is evidence to suggest that the findings were not because of regression to the mean or possible response bias brought about by a wish to “please” the provider. Neither of these phenomena would be expected to vary according to adherence to the intervention model.

Finally, it is highly improbable that the observed changes in care-process outcomes and measures of patient/parental confidence (eg, increased use of asthma action plans, documentation of asthma severity, and increases in patient confidence in self-management) came about as a natural or spontaneous outcome of the passage of time alone. It is very likely that these changes were the direct result of the demonstration. This interpretation is supported by the correlations between the degree of model adherence and care-process outcomes, as well as by the correlation between care processes and clinical outcomes.

In an earlier meta-analysis of asthma education programs, Wolf et al³³ found that interventions to teach aspects of self-management for children with asthma yielded only modest improvements in clinical outcomes (eg, asthma symptoms and urgent care visits). In later studies, programs that featured a dedicated outreach person to interact with, educate, and support families, often in a home setting, tended to report relatively stronger clinical outcomes.^{13,22,32,34-38} Other studies have successfully used CQI strategies to alter management decisions in asthma.^{20,21,34,37,39} This demonstration combined CQI strategies and CHW-provided educational efforts, home visits, and environmental assessments to “capture” and extend many of the successful components of intervention studies that have been reported in the literature.

There are several key strategies incorporated into the design that are important to highlight when considering the replication or future application of this demonstration to other populations: (1) the use of intense centralized TA throughout the intervention in support of CQI as the method for practice improvement; (2) CHWs with direct roles in the clinical practice and CQI team; (3) the application of clinical practices based on NAEPP guidelines to set goals for clinical management; and (4) giving clinic teams the freedom to identify and tailor quality improvement strategies to their particular circumstances. It is not possible to identify which of these factors, either singly or in combination, were of greatest importance in producing the observed outcomes.

With respect to the use of the CQI process, we con-

sistently emphasized the application of CQI principles via external TA and the participation of a knowledgeable and well-respected clinician champion at each site to lead the process. We also emphasized shared team responsibilities at each site for decision-making and the use of objectively measured outcomes to plan and evaluate quality improvement efforts. There was overall consistency in the application of the CQI process and NAEPP guidelines to set clinical asthma management goals. We also encouraged the development of local clinic-by-clinic variations in the selection of specific quality improvement strategies (eg, in the way asthma action plans were used and documented), because these were based on rational choices made by the individual clinic CQI teams, contingent on their local assessment of improvement opportunities. This approach increased the site-specific acceptance or “ownership” of the decision-making process. We believe that the parallel processes of allowing clinics to identify and tailor quality improvement strategies to their local practice needs, combined with the emphasis on implementing a consistent across-site CQI process guided by NAEPP guidelines for performance goal setting, was key to the success of the project.

A cost-effectiveness analysis of this demonstration is in progress. Preliminary results are positive, even when considering the costs of project setup and the central CQI TA team (J. Riddle, PhD, written communication, 2007). In light of a relatively negative report of the effect of a CQI intervention in childhood asthma in private practices,³¹ we note that our experience differs from most CQI interventions at clinical sites by the aspect of continuous guidance and follow-up throughout the intervention. Most of the sites were relatively uninformed regarding CQI at the inception of the project, and at least a year was required before we were confident in their ability to self-guide the process. Staff turnover was also an issue at some sites. Several clinics endured changes in core staff that may have had a strongly negative effect on some clinics’ scores on satisfaction and measures of parental confidence in care. The major differences in and among the “clinical cultures” of individual private practices, staff-model health maintenance organizations, and community clinics serving disadvantaged populations may also account for the apparent greater success of this demonstration in comparison with other trials.

IMPLICATIONS FOR PRACTICE

Clinicians caring for disadvantaged children are encouraged to focus efforts toward improving both the quality-of-care processes and the associated outcomes via the integration of evidence-based care into their practice. A CQI process that incorporates the use of data, includes multidisciplinary team members in the context of shared decision-making, directly applies CQI methods in the planning and decision-making process with leadership of a well-respected clinician champion who is versed in the

CQI process provides an optimal framework for improvements in both practice and disease management. In the community clinic setting, the addition of a CHW or health educator to the team in a highly integrated and inclusive fashion may offer a greater likelihood of success by widening the perspective of the clinical care team to include more information regarding community contextual factors that may have an effect on reaching asthma management goals.

As noted above, we are unable to disentangle the relative effects of the CQI process, the CHW, and the guidance by the TA team on the observed outcome improvements. From a practical standpoint, it is probably more feasible to implement a CQI culture change in clinical practice settings, because this is presumably less resource intensive than also identifying resources to hire a CHW. Given the magnitude of the effects that we observed, it is feasible that incorporating a robust CQI process would lead to substantial improvements in asthma management outcomes, albeit probably not equivalent to the magnitude of changes that would likely occur with all of the demonstration components in place.

Future work in this area includes the application of a less resource-intense model to a larger number of clinics using similar emphasis on the application of the CQI process, clinician leadership, evidence-based care, and CHWs but less of the centralized TA. This “leaner” model is currently being applied in the Best Practices in Childhood Asthma Study, which is being conducted by us in 18 communities across California.

CONCLUSIONS

To our knowledge, this project was one of the first attempts to institute and conduct a multisite intervention of this magnitude in a population of economically disadvantaged multiethnic school-aged children with asthma and to document resultant changes in the care process and consequent clinical outcomes. Components of proven interventions were strategically combined into an integrated approach that emphasized a consistent, centrally guided CQI strategy to change clinic systems and processes for asthma care, along with the involvement of CHWs in home assessment and outreach to the community. The overall multidisciplinary quality improvement-based approach used in this demonstration seems to offer the possibility of substantially improved asthma outcomes for children and their families, especially among low-income, multiethnic children.

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